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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/518,814
Filing Date: December 21, 2004
Appellant(s): SAKATA ET AL.

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EXAMINER'S ANSWER

This is in response to the appeal brief filed March 26, 2009 appealing from the Office action mailed May 28, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

Whether claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hikida et al. (US Patent No. 6,063,777).

Whether claims 1-2 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hikida et al. (US Patent No. 6,063,777) as applied to claims 13 and 14 above in view of Levy (Trends Biotechnology, 1995).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Hikida et al.	US Patent No. 6,063,777	May 2000
Levy	*Trends Biotechnology*, 1995, 13 (1), pp. 14-18.	

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hikida et al. (US Patent No. 6,063,777).

Hikida teaches an iminochlorine aspartic acid derivative of the compound of formula I and pharmaceutically acceptable salts thereof (abstract, column 1, lines 8-10), in particular the sodium salt (column 6, lines 56-59).

Hikida further teaches that the iminochlorine aspartic acid derivative of the compound of formula I, a photosensitizer molecule, is administered in photodynamic therapy (PDT) as a new method for the treatment of cancer. The porphyrin derivative is taken up by the cancerous tissues in the subject, which is then followed by laser radiation causing selective destruction of the cancerous tissues (column 1, lines 15-26). Additionally, Hikida teaches that the use of this compound in PDT is extremely useful as a diagnostic agent for cancers and ophthalmic neurovascularization (column 13, lines 4-6, and the claims).

Hikida does not explicitly teach the use of the iminochlorine aspartic acid derivative of the compound of formula I for determining the location of a sentinel lymph node and the presence of cancer metastasis by PDT.

It would have been obvious to one of ordinary skill in the art to have employed the iminochlorine aspartic acid derivative of the compound of formula I as taught by Hikida and used them to determine the location of a sentinel lymph node and the presence of cancer metastasis by PDT. One would be motivated to employ said compounds because Hikida teaches that these compounds are extremely useful as diagnostic agents. Thus one would expect with a reasonable degree of certainty that the administration of said compounds would be successful in detecting the sentinel lymph node and as a result detecting the presence of metastasis.

Claims 1-2 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hikida et al. (US Patent No. 6,063,777) as applied to claims 13 and 14 above in view of Levy (Trends Biotechnology, 1995).

Hikida is discussed above.

Hikida does not explicitly teach the use of the iminochlorine aspartic acid derivative of the compound of formula I for the treatments of rheumatoid arthritis and inflammatory keratosis.

Levy teaches that the photosensitizer molecules that have been used both clinically and experimentally in PDT tend to accumulate selectively and be retained by abnormal or hyperproliferative cells, particularly those fed by neovasculature, such as cancer tissue (page 14, column 1, lines 16-20).

Levy further teaches that most photosensitizers currently being investigated in clinical studies exert their effect on tumors by their selective accumulation in both rapidly dividing or activated cells and neovasculature, any disease in which the underlying pathology involves these characteristics is a potential candidate for PDT (page 14, column 2, lines 10-19). Table 1 gives a partial list of such diseases and includes only those conditions for which there is some evidence, either clinical or preclinical, that PDT may have efficacy (page 16). These include psoriasis (i.e., inflammatory keratosis), macular degeneration of the retina, autoimmune conditions (i.e. rheumatoid arthritis), atherosclerosis and restenosis (page 16, lines 11-18). This

apparently disparate group of diseases has common underlying features in their pathology, which provide a common ground for treatment with PDT.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have applied the iminochlorine aspartic acid derivative of the compound of formula I as taught by Hikida for methods of treating the diseases as taught by Levy.

One would be motivated to employ the iminochlorine aspartic acid derivative taught by Hikida to treat the ailments taught by Levy because the compounds taught in both references, though different, are used to both detect and treat cancer in addition to being photosensitizers. Both references teach their respective compounds as having the potential of being useful in PDT. Thus one would expect with a reasonable degree of success that a photosensitizing compound such as the iminochlorine aspartic acid derivatives taught by Hikida that can diagnose and treat cancer can also be employed to treat the ailments taught by Levy, one of which is cancer.

Furthermore, because of its quick metabolism in a living body, PDT exhibits no toxicity against abnormal cells and would increase patient compliance as a result.

(10) Response to Argument

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hikida et al. (US Patent No. 6,063,777) should be affirmed.

Appellant argues that review of Hikida reveals that it does not mention any of the following words: sentinel, lymph, node, and metastasis. Although the reference indicates that the compounds described therein might be useful for diagnosing cancer, based on the accumulability of the compound in cancer cells and the rapid excretion from normal cells, there is no indication anywhere in the reference that the compounds would accumulate in the sentinel lymph node. Further, there is no indication that aggregation of the compounds in the sentinel lymph node might be at all indicative of metastasis.

As per claims 13 and 14, the reference does not teach the location of the sentinel lymph node per se. However, because Hikeda teaches the compound as a method of treating cancer and that the compound is useful as a diagnostic agent, it would be obvious that in addition to locating cancers that it would also be obvious to try to locate the sentinel lymph node (i.e. the first lymph nodes reached by metastasizing cancer cells). It is the opinion of the Examiner that if an agent is useful as a diagnostic and therapeutic agent that it will necessarily treat tumors including those that have metastasized from it. Further, it would at least be obvious to try, with a reasonable expectation of success, to employ said agent to locate a specific site of metastasizing cancer, namely the sentinel lymph node.

Claims 1-2 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hikida et al. (US Patent No. 6,063,777) as applied to claims 13 and 14 above in view of Levy (Trends Biotechnology, 1995), should be affirmed.

Appellant argues that there is nothing in Levy which even suggests that the photodynamic therapy would be effective for treating all of the numerous and varied

conditions falling within the classification "inflammatory keratosis". Accordingly, the skilled artisan would have no reason to modify the teachings of Levy so as to encompass treating inflammatory keratosis rather than psoriasis. Further, the reference teaches that some photosensitizers have undesireable properties, for instance a photosensitizer may have an activation wavelength of light that is too low, thereby preventing adequate light penetration and limiting the size and depth of tumors that could be effectively treated. Other issues associated with known photosensitizers include the clearance rate of the compound, a clearance rate that is too slow may render a patient too sensitive to light exposure and for instance, preclude a patient from being exposed to sunlight. A clearance rate that is too fast could preclude adequate accumulation of the photosensitizer, thereby rendering any treatment attempts unsuccessful. Still further, the rate and degree to which the compound selectively accumulates in tumors is important and certain minimum thresholds must be met before a compound can be suitable for photodynamic therapy.

As such, not only would the skilled artisan not consider Levy to adequately teach a method of treating rheumatoid arthritis or inflammatory keratosis with photodynamic therapy, because the statements in Levy are speculative, the skilled artisan would not be inclined to try to substitute the photosensitizers described in the reference with other potential sensitizers.

Though the photodynamic therapy (PDT) agent taught by Levy is different than that of Applicant's, the agents are used to both detect and treat cancer and are employed in PDT. As discussed above rheumatoid arthritis and psoriasis (a type of inflammatory keratosis) are also taught as being conditions that are potential candidates for PDT. Thus in light of Levy, it would have been obvious to also employ the iminochlorine aspartic acid derivative of Hikida for treating similar ailments. Additionally, with respect to Applicant's arguments that Examiner equates psoriasis with inflammatory keratosis, Examiner respectfully notes that psoriasis is a species of inflammatory keratosis. Therefore, if one treats psoriasis then one is necessarily treating a type of inflammatory keratosis and thus meeting the claim limitation.

Additionally, Applicant contends that the reference teaches that some photosensitizers have undesirable properties including the effectiveness of the

photosensitizer to wavelength activation and how well a tumor is penetrated and clearance rate. Examiner respectfully notes that although these may be issues to consider, it is not a reason to deter one of ordinary skill in the art from at least trying to employ the iminochlorine aspartic acid derivative as a method of treating inflammatory keratosis and rheumatoid arthritis. The issues mentioned above are always a concern and are considered parameters that one of ordinary skill in the art must address and optimize. Further, Levy teaches these drawbacks for the PDT agent PHOTOFRIN®, thus is still would not deter one from employing the iminochlorine aspartic acid derivative to treat the instant diseases. There is nothing that specifically teaches away from said compound. Additionally, Levy goes on to teach newer generations of photosensitizers that overcome these limitations, further motivating one in the art to try to employ other agents, namely the agent of interest, with a reasonable degree of achieving success of treating said ailments. Thus there is no reason why, in the absence of unexpected results, that one in the art would not employ one PDT agent over another, with a reason degree of success, in the treatment of inflammatory keratosis and rheumatoid arthritis in view of Levy's teachings.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617

Conferees:

/Johann R. Richter/

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/SAHAR JAVANMARD/

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